

REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on July 18, 2008, claims 5-8 were rejected under 35 U.S.C. 112, second paragraph; claim 1 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998) and further in view of Gagnon (1997) in view of Elliot (US 1,885,401) and further in view of Beaven (GB 2215173A) and Astrauskas et al. (US 3,953,582); and claims 1, 5-12 and 24-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998), in view of Gagnon (1997), in view of Brock et al. (1991), in view of Nahir (EP 0 555 573 A1) and in view of Elliot (US 1,885,410) and further in view of Beaven (GB 2215173A) and Astrauskas et al. (US 3,953,582). For the reasons set forth below, Applicant submits that the prior art fails to teach or suggest all the claim limitations. Thus, Applicant's claims are not obvious in view of the prior art references.

Claims 1, 5-12 and 24-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable. M.P.E.P. § 2141 sets forth the *Graham* factual inquiries that should be considered when making an obviousness rejection under Section 103: 1) ascertaining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. (Citing *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966).) In addition, M.P.E.P. §§ 2141 and 2142 set forth that "the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." (Citing *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S., 82 USPQ2d 1385 (2007).)

The M.P.E.P. provides several examples of rationales that can support a rejection under 35 U.S.C. § 103, namely:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

(M.P.E.P. §§ 2141 & 2143, emphasis added.) As may be seen from the emphasized portions of the above potential rationales, each rationale is dependent on showing known elements from the prior art corresponding to the limitations of the claimed invention. Each rationale therefore depends on: 1) satisfying the *Graham* inquiry, showing that the scope and content of the prior art included each limitation contained in the claimed invention, and 2) satisfactorily showing that one of ordinary skill in the art would take the art teachings to overcome the identified differences under *Graham* between the claimed invention and the individual teachings of the prior art.

Applicant respectfully submits that the references in the Office Action, either alone or in combination, do not teach or suggest all the limitations claimed in the claim set provided herein. As indicated above in the amended claim section, claim 1 recites a “method for processing and administering an improved *Morinda citrifolia* product with increased capacity to scavenge lipid hydroperoxides and superoxide anion free radicals within the body, said method comprising: harvesting the fruit from a *Morinda citrifolia* plant; allowing fruit to ripen for 1 to 14 days; preparing said harvested fruit for extraction of the juice therefrom, wherein said preparing comprises: placing the ripened fruit in plastic lined containers, and holding the fruit in said containers for 1 to 30 days extracting the juice from said prepared fruit to obtain said *Morinda citrifolia* fruit juice, wherein said extraction comprises: [...] filtering by centrifuge decanter with a screen filter size between 200 and 500 microns, wherein said operating filter pressure may range from about 0.1 psig to 1000 psig combining said processed *Morinda citrifolia* product with other ingredients [...]”.

Applicant submits that the cited references do not teach every aspect of the claimed invention, as amended. The method of making the product, and the various constitutive elements added to the product before delivery have a significant effect on lipidperoxidation inhibition. The specification of the present invention and the art cited against the present application outline the

importance of the harvesting and processing steps in order to produce an improved *Morinda citrifolia* product, which has increased and unexpected capacity to inhibit lipidperoxidation.

Chye, Schechter, Gagnon, Brock, Nahir, Elliot, Beven and Astrauskas fail to teach or fairly suggest the particular processing steps that produce a *Morinda citrifolia* product developed particularly to scavenge lipid hydroperoxides. Rather, Chye provides a non-enabling disclosure, which indicates merely that “noni-juice is the new darling of health-conscious Malaysians”. Schechter indicates that noni fruit contains vitamin C, selenium, and other substances that counteract inflammation and absorb free radicals in the body. However, Schetheter does not disclose processing steps claimed herein that produce the surprising scavenging properties claimed in the present invention. And Elliot teaches a method of processing oranges into juice where the oranges are crushed, separating the rind and seeds from the pulp, juice, oil with a certain residue of seeds and rind. Elliot further teaches that the product is passed through a revolving screen of suitably large mesh to isolate the juice and that the separated liquid is subsequently passed through a centrifugal separator one or more times to remove the greater portion of the peel oil from the liquid mixture. Elliot does not teach allowing the fruit to ripen for 0 to 14 days; preparing said harvested fruit for extraction of the juice therefrom, wherein said preparing comprises: placing the ripened fruit in plastic lined containers, and holding the fruit in said containers for 0 to 30 days or the presently claimed method of extrating the juice from the prepared fruit to obtain said *Morinda citrifolia* fruit juice, wherein the extraction steps comprise the specific filtering requirements of filtering by centrifuge decanter with a screen filter size between 1 and 2000 microns, wherein said operating filter pressure may range from about 0.1 psig to 1000 psig. Accordingly, Elliot fails to recite each of the processing limitation and would not have put one skilled in the art in possession of the presently claimed juice product, even when combined with Chye, Schechter, Gagnon, Brock, Nahir, Beven and Astrauskas.

The importance of the manufacturing steps utilized to process *Morinda citrifolia* products is confirmed in various published articles and by research performed by Applicant. The article [“Drug Development; The Pain Killer Tree: An Ancient Remedy Rediscovered” (hereinafter “Drug Development”)] clearly conveys that unexpected results were achieved when different processing steps are utilized. In particular, Drug Development taught that modifying a single processing step, utilizing freeze drying alone improved the efficiency of the noni product 267%

over the closest other dried noni product. Congruent with the disclosure found in "Drug Development," Chye discloses the concern that certain methods of manufacturing produce greater quality products, and that a Mr. Story and Wadsworth developed methods of harvesting, processing and bottling the juice that did not sacrifice the important effects natural ingredients.

As the cited references fail to disclose or suggest all of the claim limitations of independent claims of the present invention, and further fail to suggest modifying the reference as suggested by the Examiner, the present invention is not obvious in view of such references.

CONCLUSION

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

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Respectfully submitted,



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